



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket No. FDA-2017-N-0011]

Requirements to Submit Prior Notice of Imported Food; Technical Amendments

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendments.

SUMMARY: The Food and Drug Administration (FDA or we) is amending the prior notice of imported food regulations to reflect a change in the electronic data interchange system and its expanded capabilities, to correct inaccurate number designations in section headings, and to reflect a change in an office's name. This action is ministerial or editorial in nature.

DATES: This rule is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Jennifer Thomas, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2094.

SUPPLEMENTARY INFORMATION:

I. Background

Section 801(m) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 381(m)) requires that FDA establish regulations requiring that those persons importing articles of food or offering articles of food for import into the United States submit certain information about imported foods before the products' arrival in the United States. We have established the

regulations at title 21, Code of Federal Regulations (CFR) part 1, subpart I (21 CFR 1.276 to 1.285). Section 801(m) of the FD&C Act also provides that an article of food imported or offered for import is subject to refusal of admission into the United States if adequate prior notice has not been provided to FDA. Our regulations in 21 CFR part 1, subpart I, include information on when to submit prior notice, how to submit prior notice, and what information is required in a prior notice.

## II. Description of the Technical Amendments

We are making technical amendments in our prior notice regulations in part 1, subpart I (§§ 1.276 to 1.285), to:

- Reflect the change in an electronic data interchange system and its expanded capabilities;
- correct paragraph number designations in certain introductory text paragraphs; and
- revise the name of an FDA office receiving certain information.

The technical amendments are ministerial or editorial in nature and are not intended to modify any substantive requirements.

### A. Revising An Electronic Data Interchange System and Recognizing its Expanded Capabilities

Our current regulations, at §§ 1.279, 1.280, 1.281, and 1.282, refer to the “Automated Broker Interface/Automated Commercial System (ABI/ACS)” or “Automated Broker Interface of the Automated Commercial System (ABI/ACS).” We are amending these regulations to reflect the change of the electronic data interchange system from “Automated Broker Interface/Automated Commercial System (ABI/ACS)” or “Automated Broker Interface of the Automated Commercial System (ABI/ACS)” to “Automated Broker Interface/Automated Commercial Environment/International Trade Data System (ABI/ACE/ITDS).” In the Federal

Register of May 16, 2016 (81 FR 30320), the Department of Homeland Security's U.S. Customs and Border Protection (CBP) issued a notice announcing that the Automated Commercial Environment (ACE) will be the sole electronic data interchange (EDI) system authorized by the Commissioner of CBP for processing electronic entries and entry summaries associated with the entry types specified in the notice, for merchandise that is subject to our import requirements. The notice also announced that the Automated Commercial System (ACS) will no longer be a CBP-authorized EDI system for purposes of processing these electronic filings. Therefore, we are revising our regulations at §§ 1.279, 1.280, 1.281, and 1.282 by replacing all references to the "Automated Broker Interface/Automated Commercial System (ABI/ACS)" and "Automated Broker Interface of the Automated Commercial System (ABI/ACS)" with "Automated Broker Interface/Automated Commercial Environment/International Trade Data System (ABI/ACE/ITDS)" to accurately identify the current EDI system. We note, however, that there is no change in the FDA Prior Notice System Interface (FDA PNSI).

Additionally, current § 1.280 states that, for purposes of submitting prior notice, prior notice for articles that have been refused under section 801(m)(1) of the FD&C Act and our regulations must be submitted through the FDA PNSI until such time as we and CBP issue a determination that ACS or its successor system can accommodate such transactions. In addition, current § 1.281 describes what information must be provided in the prior notice and states that, until such time as we and CBP issue a determination that ACS can accommodate such transactions, the tracking number may not be submitted in lieu of other certain information if the prior notice is submitted via ABI/ACS. Furthermore, if an article of food is arriving by express consignment operator or carrier, our current regulations state that the tracking number can only be submitted in certain circumstances when neither the submitter nor transmitter is the express

consignment operator or carrier, and the prior notice is submitted via the FDA PNSI. We are revising the regulations to remove these limitations because the new ACE EDI system can accommodate such transactions. These faster, streamlined, and automated processes allow traders to submit tracking numbers much more easily. Therefore, we are removing the limitation that the tracking number may not be submitted in lieu of certain other information throughout the prior notice regulations.

Furthermore, with the tracking number, we can learn the information we need to make entry determinations, such as port, date and time of arrival, airway bill, bill of lading, and vessel name and voyage or flight number. Removing the condition that the transmitter or submitter cannot be the operator or carrier gives submitters more options for providing the information we require. Accordingly, the technical amendment provides greater flexibility to industry while also allowing us to screen imported food articles adequately.

These changes are deregulatory in nature because they lessen the burden imposed on traders without impairing our ability to ensure the safety of imported food. The expanded capabilities of the new ACE EDI system allow for additional flexibility in submitting certain information. Because of technical limitations of the former system, in certain cases the prior notice information could be submitted only via FDA PNSI because ACS could not accommodate such transactions. For example, ACS could not accept the tracking number in lieu of other certain information such as port, date and time of arrival, airway bill, bill of lading, vessel name, and voyage or flight number.

The new ACE EDI system can accommodate these transactions, which results in additional flexibility to industry. Some filers no longer have to use two systems to file prior notice information for the same food import line. In addition, FDA staff will be able to more

efficiently process import entry submissions and more quickly make the initial import entry determination for food imports, in furtherance of our goal to ensure the safety of imported food.

#### B. Correcting Number Designations in Headings and Changing an FDA Office's Title

The FDA Food Safety Modernization Act (FSMA) (Pub. L. 111-353) was signed into law on January 4, 2011. Section 304 of FSMA amended section 801(m)(1) of the FD&C Act to require that a person submitting prior notice of imported food, in addition to other information already required, report “any country to which the article has been refused entry.” On May 5, 2011, we issued an interim final rule (2011 IFR) (76 FR 25542) implementing section 304 of FSMA. Specifically, the 2011 IFR amended § 1.281 by adding a new requirement to paragraphs (a), (b), and (c) that any person submitting prior notice of imported food report the name of any country to which the article has been refused entry. However, the 2011 IFR neglected to make corresponding edits to change the paragraph number designations in the introductory text for paragraphs (a), (b), and (c) in § 1.281 to reflect the additional data element as added by the 2011 IFR and affirmed in a final rule published on May 30, 2013 (78 FR 32359). The technical amendment corrects those designations.

Furthermore, current § 1.285(i)(2) refers to the “FDA Prior Notice Center.” The office is now named the “FDA Division of Food Defense Targeting,” so we are amending § 1.285(i)(2) accordingly.

### III. The Administrative Procedure Act

Publication of this document constitutes final action of these changes under the Administrative Procedure Act (APA) (5 U.S.C. 553). Under 5 U.S.C. 553(b)(3)(B) of the APA, an Agency may, for good cause, find (and incorporate the finding and a brief statement of reasons in the rules issued) that notice and public comment procedure on a rule is impracticable,

unnecessary, or contrary to the public interest. We have determined that notice and public comment are unnecessary because these amendments only make technical or non-substantive, ministerial changes to reflect the change in an electronic data interchange system and its expanded capabilities, correct number designations in headings as a result of the FSMA amendments to prior notice, and amend the name of an FDA office. For these reasons we have determined that publishing a notice of proposed rulemaking and providing opportunity for public comment is unnecessary.

In addition, we find good cause for these amendments to become effective on the date of publication of this action. The APA allows an effective date less than 30 days after publication as “provided by the agency for good cause found and published with the rule” (5 U.S.C. 553(d)(3)). A delayed effective date is unnecessary in this case because the amendments do not impose any new regulatory requirements on affected parties. As a result, affected parties do not need time to prepare before the rule takes effect. Therefore, we find good cause for this correction to become effective on the date of publication of this action.

#### IV. Paperwork Reduction Act of 1995

This final rule refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 1, subpart I, have been approved under OMB control number 0910-0520.

##### List of Subjects in 21 CFR Part 1

Cosmetics, Drugs, Exports, Food labeling, Imports, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 1 is amended as follows:

## PART 1--GENERAL ENFORCEMENT REGULATIONS

1. The authority citation for part 1 continues to read as follows:

Authority: 15 U.S.C. 1333, 1453, 1454, 1455, 4402; 19 U.S.C. 1490, 1491; 21 U.S.C. 321, 331, 332, 333, 334, 335a, 342, 343, 350c, 350d, 350e, 350j, 350k, 352, 355, 360b, 360ccc, 360ccc-1, 360ccc-2, 362, 371, 373, 374, 379j-31, 381, 382, 384a, 384b, 384d, 387, 387a, 387c, 393; 42 U.S.C. 216, 241, 243, 262, 264, 271; Pub. L. 107-188, 116 Stat. 594, 668-69; Pub. L. 111-353, 124 Stat. 3885, 3889.

2. Amend §1.279 by revising paragraph (b)(1) to read as follows:

### § 1.279 When must prior notice be submitted to FDA?

\* \* \* \* \*

(b) \* \* \*

(1) If prior notice is submitted via the Automated Broker Interface/Automated Commercial Environment/International Trade Data System (ABI/ACE/ITDS), you may not submit prior notice more than 30-calendar days before the anticipated date of arrival.

\* \* \* \* \*

3. Amend § 1.280 by revising paragraphs (a)(1) and (2) and (b) to read as follows:

### § 1.280 How must you submit prior notice?

(a) \* \* \*

(1) The U.S. Customs and Border Protection (CBP) Automated Broker Interface/Automated Commercial Environment/International Trade Data System (ABI/ACE/ITDS); or

(2) The FDA PNSI at <https://www.access.fda.gov/>. You must submit prior notice through the FDA Prior Notice System Interface (FDA PNSI) for articles of food imported or offered for import by international mail, and other transaction types that cannot be made through ABI/ACE/ITDS.

(b) If a customhouse broker's or self-filer's system is not working or if the ABI/ACE/ITDS interface is not working, prior notice must be submitted through the FDA PNSI.

\* \* \* \* \*

4. Amend § 1.281 by revising paragraphs (a) introductory text, (a)(11)(iv), (a)(17)(i) and (iii), (b) introductory text, (c) introductory text, (c)(11)(iii), and (c)(17)(i) and (iii) to read as follows:

§ 1.281 What information must be in a prior notice?

(a) General. For each article of food that is imported or offered for import into the United States, except by international mail, you must submit the information for the article that is required in paragraphs (a)(1) through (18) of this section:

\* \* \* \* \*

(11) \* \* \*

(iv) Notwithstanding paragraphs (a)(11) introductory text and (a)(11)(i) through (iii) of this section, if the article of food is arriving by express consignment operator or carrier, the express consignment operator or carrier tracking number may be submitted in lieu of the information required in paragraphs (a)(11) introductory text and (a)(11)(i) through (iii) of this section.

\* \* \* \* \*

(17) \* \* \*



(i) The Airway Bill number(s) or Bill of Lading number(s), as applicable. This information is not required for an article of food when carried by or otherwise accompanying an individual when entering the United States. If the article of food is arriving by express consignment operator or carrier, the express consignment operator or carrier tracking number may be submitted in lieu of the Airway Bill number(s) or Bill of Lading number(s), as applicable;

\* \* \* \* \*

(iii) For food arriving by air carrier, the flight number. If the article of food is arriving by express consignment operator or carrier, the express consignment operator or carrier tracking number may be submitted in lieu of the flight number;

\* \* \* \* \*

(b) Articles arriving by international mail. For each article of food that is imported or offered for import into the United States by international mail, you must submit the information for the article that is required in paragraphs (b)(1) through (12) of this section:

\* \* \* \* \*

(c) Refused articles. If the article of food has been refused under section 801(m)(1) of the act and under this subpart, you must submit the information for the article that is required in paragraphs (c)(1) through (19) of this section. However, if the refusal is based on § 1.283(a)(1)(iii) (Untimely Prior Notice), you do not have to resubmit any information previously submitted unless it has changed or the article has been exported and the original prior notice was submitted through ABI/ACE/ITDS. If the refusal is based on § 1.283(a)(1)(ii), you should cancel the previous submission per § 1.282(b) and (c).

\* \* \* \* \*

(11) \* \* \*

(iii) Notwithstanding paragraphs (c)(11) introductory text and (c)(11)(i) and (ii) of this section, if the article of food arrived by express consignment operator or carrier, the express consignment operator or carrier tracking number may be submitted in lieu of the information required in paragraphs (c)(11) introductory text and (c)(11)(i) and (ii) of this section.

\* \* \* \* \*

(17) \* \* \*

(i) The Airway Bill number(s) or Bill of Lading number(s), as applicable; however, this information is not required for an article of food when carried by or otherwise accompanying an individual when entering the United States. If the article of food arrived by express consignment operator or carrier, the express consignment operator or carrier tracking number may be submitted in lieu of the Airway Bill number(s) or Bill of Lading number(s), as applicable;

\* \* \* \* \*

(iii) For food that arrived by air carrier, the flight number. If the article of food arrived by express consignment operator or carrier, the express consignment operator or carrier tracking number may be submitted in lieu of the flight number;

\* \* \* \* \*

5. Amend § 1.282 by revising paragraph (c) to read as follows:

§ 1.282 What must you do if information changes after you have received confirmation of a prior notice from FDA?

\* \* \* \* \*

(c) If you submitted the prior notice via ABI/ACE/ITDS, you should cancel the prior notice via ACE by requesting that CBP cancel the entry.

6. Amend § 1.285 by revising the first sentence in paragraph (i)(2) to read as follows:

§ 1.285 What happens to food that is imported or offered for import from unregistered facilities that are required to register under subpart H of this part?

\* \* \* \* \*

(i) \* \* \*

(2) The FDA Division of Food Defense Targeting must be notified of the applicable registration number in writing.\* \* \*

\* \* \* \* \*

Dated: March 24, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

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